

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION FOR LETTERS PATENT

Cardiac Stimulation Devices and Methods for Measuring Impedances Associated with the Left Side of the Heart

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1 **RELATED APPLICATION**

2 This application stems from and claims priority to U.S. Provisional
3 Application Serial No. 60/204,310, filed on May 15th, 2000, the disclosure of
4 which is incorporated by reference herein.

5

6 **TECHNICAL FIELD**

7 The present invention generally relates to cardiac rhythm management
8 devices, such as implantable cardioverter-defibrillators (ICDs) and pacemakers, or
9 combinations thereof. The present invention more particularly relates to such
10 devices which utilize one or more electrodes implanted on the left-side of the heart
11 for providing desired stimulation therapy and for measuring physiological
12 parameters based on measured electrical impedances.

13

14 **BACKGROUND**

15 Cardiac rhythm management devices, including implantable devices, are
16 well known in the art. Such devices may include, for example, implantable
17 cardiac pacemakers, cardioverters or defibrillators. The devices are generally
18 implanted in an upper portion of the chest, in either the left or right side depending
19 on the type of the device, beneath the skin of a patient within what is known as a
20 subcutaneous pocket. The implantable devices generally function in association
21 with one or more electrode-carrying leads which are implanted within the heart.
22 The electrodes are typically positioned within the right side of the heart, either the
23 right ventricle or right atrium, or both, for making electrical contact with their
24 designated heart chamber. Conductors within the leads couple the electrodes to
25 the device to enable the device to deliver the desired stimulation therapy.

1 Traditionally, therapy delivery has been limited to the right side of the
2 heart. The reason for this is that implanted electrodes can cause blood clot
3 formation in some patients. If a blood clot were released from the left-side of the
4 heart, as from the left ventricle, it could pass directly to the brain resulting in a
5 paralyzing or fatal stroke. However, a blood clot released from the right side of
6 the heart, as from the right ventricle, would pass into the lungs where the filtering
7 action of the lungs would prevent a fatal or debilitating embolism in the brain.

8 Recently, new lead structures and methods have been proposed and even
9 practiced for delivering cardiac rhythm management therapy from or to the left-
10 side of the heart. These lead structures and methods avoid electrode placement
11 within the left atrium and left ventricle of the heart by lead implantation within the
12 coronary sinus and/or the great vein of the heart which communicates with the
13 coronary sinus and extends down towards the apex of the heart. As is well known,
14 the coronary sinus passes closely adjacent the left atrium and extends into the
15 great vein adjacent the left ventricular free wall. The great vein then continues
16 adjacent the left ventricle towards the apex of the heart.

17 It has been observed that electrodes placed in the coronary sinus and great
18 vein may be used for left atrial pacing, left ventricular pacing, and even
19 cardioversion and defibrillation. This work is being done to address the needs of a
20 patient population with left ventricular dysfunction and congestive heart failure.
21 This patient class has been targeted to receive pacing leads intended for left
22 ventricular pacing, either alone or in conjunction with right ventricular pacing.
23 When delivering such therapy to these patients, it would be desirable to provide
24 device-based measurements of left ventricular function for both monitoring and
25 therapy delivery.

1 It is known in the art that device-based impedance measurements offer one
2 method for assessing patient condition. It is also well known, however, that bio-
3 impedance measurements can be confounded by signals not directly related to the
4 desired physiology to be measured. For example, a measurement of impedance
5 from a unipolar tip electrode in the right ventricular apex will contain signal
6 components related to respiration, and right ventricular, left ventricular, and aortic
7 hemodynamics. Filtering of the signal can help to isolate the various desired
8 signals, but the filtering required to accurately isolate the desired signals are often
9 not feasible in an implantable cardiac rhythm management device.

10 It is also known that localization of the desired signals is improved by
11 making proper choice of electrode configurations between which impedance
12 measurements are made. For example, a transchamber impedance technique is
13 known wherein impedance measurements are made between electrodes in the right
14 atrium and right ventricle to assist in isolating the right ventricular hemodynamics.

15 The advent of cardiac leads for delivering therapy to the left-side of the
16 heart which are often placed in the coronary sinus and great cardiac vein require
17 new techniques for measurement of functional parameters of, or associated with, a
18 heart. As will be seen hereinafter, the present invention addresses those needs.

19
20 **SUMMARY**

21 Methods of and systems for measuring impedance, and for measuring at
22 least one physiological parameter for assessing a patient's cardiac condition based
23 on left heart impedance measurements are described. Various embodiments
24 establish a current flow through a left side of the heart and measure a voltage
25 between a first location on or in the left side of the heart and a second location

1 within the human body while establishing the current flow. The inventive
2 techniques and systems can be used for, among other things, measuring
3 progression or regression of myocardial failure, dilation, or hypertrophy,
4 pulmonary congestion, myocardial contractility, or ejection fraction. The
5 measured voltage, related to left heart impedance, can be used to monitor patient
6 condition for diagnostic purposes or to adapt pacing or defibrillation therapy.
7 Therapy adaptation can include controlling pacing modes, pacing rates, or
8 interchamber pacing delays, for example.

9 Various embodiments still further provide systems for measuring at least
10 one physiological parameter of a patient's cardiac condition wherein the system
11 includes a current source for establishing a current flow through a left side of the
12 heart, measurement circuitry that measures a voltage between a first location on or
13 in the left side of the heart and a second location within the human body while
14 establishing the current flow, and control circuitry that responds to the measured
15 voltage for adjusting stimulation therapy. Measurements of the physiological
16 parameter(s) can take place utilizing many different electrode polarity
17 configurations, e.g. bipolar, tripolar, and quadrapolar configurations.

18

BRIEF DESCRIPTION OF THE DRAWINGS

19

20 The following description is of the best mode presently contemplated for
21 practicing the invention. This description is not to be taken in a limiting sense but
22 is made merely for the purpose of describing the general principles of the
23 invention. The scope of the invention should be ascertained with reference to the
24 issued claims.

1 FIG. 1 is a simplified diagram illustrating an implantable stimulation device
2 in electrical communication with at least three leads implanted into a patient's
3 heart for delivering multi-chamber stimulation and shock therapy;

4 FIG. 2 is a functional block diagram of a multi-chamber implantable
5 stimulation device illustrating exemplary basic elements of a stimulation device
6 which can provide cardioversion, defibrillation and/or pacing stimulation in up to
7 four chambers of the heart;

8 FIG. 3 is a reproduction of the patient's heart shown in FIG. 1 illustrating a
9 an electrode configuration that is suitable for use in ascertaining an impedance
10 measure in accordance with one embodiment.

11 FIG. 4 is a reproduction of the patient's heart shown in FIG. 1 illustrating a
12 an electrode configuration that is suitable for use in ascertaining an impedance
13 measure in accordance with one embodiment.

14 FIG. 5 is a reproduction of the patient's heart shown in FIG. 1 illustrating a
15 an electrode configuration that is suitable for use in ascertaining an impedance
16 measure in accordance with one embodiment.

17 FIG. 6 is a reproduction of the patient's heart shown in FIG. 1 illustrating a
18 an electrode configuration that is suitable for use in ascertaining an impedance
19 measure in accordance with one embodiment.

20 FIG. 7 is a reproduction of the patient's heart shown in FIG. 1 illustrating a
21 an electrode configuration that is suitable for use in ascertaining an impedance
22 measure in accordance with one embodiment.

23 FIG. 8 is a reproduction of the patient's heart shown in FIG. 1 illustrating a
24 an electrode configuration that is suitable for use in ascertaining an impedance
25 measure in accordance with one embodiment.

1 FIG. 9 is a reproduction of the patient's heart shown in FIG. 1 illustrating a
2 an electrode configuration that is suitable for use in ascertaining an impedance
3 measure in accordance with one embodiment.

4 FIG. 10 is a reproduction of the patient's heart shown in FIG. 1 illustrating
5 a an electrode configuration that is suitable for use in ascertaining an impedance
6 measure in accordance with one embodiment.

7 FIG. 11 is a reproduction of the patient's heart shown in FIG. 1 illustrating
8 a an electrode configuration that is suitable for use in ascertaining an impedance
9 measure in accordance with one embodiment.

10 FIG. 12 is a reproduction of the patient's heart shown in FIG. 1 illustrating
11 a an electrode configuration that is suitable for use in ascertaining an impedance
12 measure in accordance with one embodiment.

13 FIG. 13 is a reproduction of the patient's heart shown in FIG. 1 illustrating
14 a an electrode configuration that is suitable for use in ascertaining an impedance
15 measure in accordance with one embodiment.

16 FIG. 14 is a reproduction of the patient's heart shown in FIG. 1 illustrating
17 a an electrode configuration that is suitable for use in ascertaining an impedance
18 measure in accordance with one embodiment.

19 FIG. 15 is a reproduction of the patient's heart shown in FIG. 1 illustrating
20 a an electrode configuration that is suitable for use in ascertaining an impedance
21 measure in accordance with one embodiment.

22 FIG. 16 is a reproduction of the patient's heart shown in FIG. 1 illustrating
23 a an electrode configuration that is suitable for use in ascertaining an impedance
24 measure in accordance with one embodiment.

1 FIG. 17 is a reproduction of the patient's heart shown in FIG. 1 illustrating
2 a an electrode configuration that is suitable for use in ascertaining an impedance
3 measure in accordance with one embodiment.

4 FIG. 18 is a reproduction of the patient's heart shown in FIG. 1 illustrating
5 a an electrode configuration that is suitable for use in ascertaining an impedance
6 measure in accordance with one embodiment.

7 FIG. 19 is a reproduction of the patient's heart shown in FIG. 1 illustrating
8 a an electrode configuration that is suitable for use in ascertaining an impedance
9 measure in accordance with one embodiment.

10 FIG. 20 is a reproduction of the patient's heart shown in FIG. 1 illustrating
11 a an electrode configuration that is suitable for use in ascertaining an impedance
12 measure in accordance with one embodiment.

13 FIG. 21 is a reproduction of the patient's heart shown in FIG. 1 illustrating
14 a an electrode configuration that is suitable for use in ascertaining an impedance
15 measure in accordance with one embodiment.

16 FIG. 22 is a reproduction of the patient's heart shown in FIG. 1 illustrating
17 a an electrode configuration that is suitable for use in ascertaining an impedance
18 measure in accordance with one embodiment.

19
20 **DETAILED DESCRIPTION**

21 The following description is of the best mode presently contemplated for
22 practicing the invention. This description is not to be taken in a limiting sense but
23 is made merely for the purpose of describing the general principles of the
24 invention. The scope of the invention should be ascertained with reference to the
25

1 issued claims. In the description of the invention that follows, like numerals or
2 reference designators will be used to refer to like parts or elements throughout.

3

4 **Exemplary Stimulation Device**

5 The following description sets forth but one exemplary stimulation device
6 that is capable of being used in connection with the various embodiments that are
7 described below. It is to be appreciated and understood that other stimulation
8 devices, including those that are not necessarily implantable, can be used and that
9 the description below is given, in its specific context, to assist the reader in
10 understanding, with more clarity, the inventive embodiments described herein.

11 FIG. 1 illustrates a stimulation device 10 in electrical communication with a
12 patient's heart 12 suitable for delivering multi-chamber stimulation and shock
13 therapy. The portions of the heart 10 illustrated include the right ventricle 14, the
14 right atrium 15, the left ventricle 17, and the left atrium 18. As used herein, the
15 left-side of the heart is meant to denote the portions of the heart encompassing the
16 left ventricle 17 and the left atrium 18 and those portions of the coronary sinus,
17 great cardiac vein, and its associated tributaries, which are adjacent the left atrium
18 and left ventricle. As will be seen hereinafter, the device 10 includes a system for
19 measuring a physiological parameter, and more particularly, the left ventricular
20 impedance corresponding to contraction of the heart 12, in accordance with
21 various embodiments described in further detail below.

22 To sense atrial cardiac signals and to provide right atrial chamber
23 stimulation therapy, the stimulation device 10 is coupled to an implantable right
24 atrial lead 20 having at least an atrial tip electrode 22, and preferably a right atrial

1 ring electrode 23, which typically is implanted in the patient's right atrial
2 appendage.

3 To sense left atrial and ventricular cardiac signals and to provide left-
4 chamber pacing therapy, the stimulation device 10 is coupled to a "coronary sinus"
5 lead 24 designed for placement in the "coronary sinus region" via the coronary
6 sinus os so as to place one or more distal electrodes adjacent to the left ventricle
7 and one or more proximal electrodes adjacent to the left atrium 18. As used
8 herein, the phrase "coronary sinus region" refers to the vasculature of the left
9 ventricle, including any portion of the coronary sinus, great cardiac vein, left
10 marginal vein, left posterior ventricular vein, middle cardiac vein, and/or small
11 cardiac vein or any other cardiac vein accessible by the coronary sinus.

12 Accordingly, the coronary sinus lead 24 is designed to receive atrial and
13 ventricular cardiac signals and to deliver: left ventricular pacing therapy using, for
14 example, a left ventricular tip electrode 25 and a left ventricular ring electrode 26;
15 left atrial pacing therapy using, for example, a first and second left atrial ring
16 electrode, 27 and 28; and shocking therapy using at least a left atrial coil electrode
17 29. For a complete description of a coronary sinus lead, refer to U.S. Patent
18 Application No. 09/457,277, titled "A Self-Anchoring, Steerable Coronary Sinus
19 Lead" (Pianca et al.); and U.S. Patent No. 5,466,254, titled "Coronary Sinus Lead
20 with Atrial Sensing Capability" (Helland), which patents are hereby incorporated
21 herein by reference.

22 The stimulation device 10 is also shown in electrical communication with
23 the patient's heart 12 by way of an implantable right ventricular lead 30 having a
24 right ventricular tip electrode 32, a right ventricular ring electrode 34, a right
25 ventricular (RV) coil electrode 36, and an SVC coil electrode 38. Typically, the

1 right ventricular lead 30 is transvenously inserted into the heart 12 so as to place
2 the right ventricular tip electrode 32 in the right ventricular apex so that the RV
3 coil electrode 36 will be positioned in the right ventricle and the SVC coil
4 electrode 38 will be positioned in the superior vena cava. Accordingly, the right
5 ventricular lead 30 is capable of receiving cardiac signals, and delivering
6 stimulation in the form of pacing and shock therapy to the right ventricle 14.

7 FIG. 2 illustrates a simplified block diagram of the multi-chamber
8 implantable stimulation device 10, which is capable of treating both fast and slow
9 arrhythmias with stimulation therapy, including cardioversion, defibrillation, and
10 pacing stimulation. While a particular multi-chamber device is shown, this is for
11 illustration purposes only, and one of skill in the art could readily duplicate,
12 eliminate or disable the appropriate circuitry in any desired combination to
13 provide a device capable of treating the appropriate chamber(s) with
14 cardioversion, defibrillation and/or pacing stimulation. In addition, it will be
15 appreciated and understood that various processing steps about to be described can
16 be implemented in the form of software instructions that are resident on a
17 computer-readable media that is located on the stimulation device. Accordingly,
18 aspects of the invention described herein extend to all forms of computer-readable
19 media, whether on the stimulation device or not, when such media contains
20 instructions that, when executed by one or more processors, implement the
21 methods described herein.

22 The stimulation device 10 includes a housing 40 which is often referred to
23 as "can", "case" or "case electrode", and which may be programmably selected to
24 act as the return electrode for all "unipolar" modes. The housing 40 may further be
25

1 used as a return electrode alone or in combination with one or more of the coil
2 electrodes 29, 36, or 38, for shocking purposes.

3 The housing 40 further includes a connector (not shown) having a plurality
4 of terminals, 42, 43, 44, 45, 46, 47, 48, 52, 54, 56, and 58 (shown schematically
5 and, for convenience, the names of the electrodes to which they are connected are
6 shown next to the terminals). While it is recognized that current devices are
7 limited to the number of terminals due to International Standards, one of skill in
8 the art could readily eliminate some of the terminals/electrodes to fit in the
9 existing device configurations and permit programmability to select which
10 terminals connect to which electrodes. However, in the near future, the standards
11 may change to permit multi-polar in-line connectors, and multiple feedthroughs
12 connectors could readily be manufactured to accommodate the configuration
13 shown in FIG. 2.

14 As such, to achieve right atrial sensing and pacing, the connector includes
15 at least a right atrial tip terminal 42 and a right atrial ring terminal 43, adapted for
16 connection to the atrial tip electrode and ring electrodes 22 and 23, respectively.

17 To achieve left chamber sensing, pacing and/or shocking, the connector
18 includes at least a left ventricular tip terminal 44, a left ventricular ring electrode
19 45, a first left atrial ring terminal 46, a second left atrial ring terminal 47, and a
20 left atrial shocking terminal 48, which are adapted for connection to the left
21 ventricular tip electrode 25, left ventricular ring 26, the first left atrial tip electrode
22 27, the second left atrial ring electrode 28, and the left atrial coil electrode 29,
23 respectively.

24 To support right chamber sensing, pacing and/or shocking, the connector
25 further includes a right ventricular tip terminal 52, a right ventricular ring terminal

1 54, a right ventricular (RV) shocking terminal 56, and an SVC shocking terminal
2 58, which are adapted for connection to the right ventricular tip electrode 32, right
3 ventricular ring electrode 34, the RV coil electrode 36, and the SVC coil electrode
4 38, respectively.

5 At the core of the stimulation device 10 is a programmable microcontroller
6 or microprocessor 60 that controls the various modes of stimulation therapy. As is
7 well known in the art, the microcontroller 60 typically includes a microprocessor,
8 or equivalent control circuitry, designed specifically for controlling the delivery of
9 stimulation therapy, and may further include RAM or ROM memory, logic and
10 timing circuitry, state machine circuitry, and I/O circuitry. Typically, the
11 microcontroller 60 includes the ability to process or monitor input signals (data) as
12 controlled by a program code stored in a designated block of memory. The details
13 of the design and operation of the microcontroller 60 are not critical to the present
14 invention. Rather, any suitable microcontroller 60 may be used that carries out the
15 functions described herein. The use of microprocessor-based control circuits for
16 performing timing and data analysis functions are well known in the art.

17 As shown in FIG. 2, an atrial pulse generator 70 and a ventricular pulse
18 generator 72 generate pacing stimulation pulses for delivery by the right atrial lead
19 20, the right ventricular lead 30, and/or the coronary sinus lead 24 via a switch
21 bank 74. It is understood that in order to provide stimulation therapy in each of
22 the four chambers of the heart, the atrial pulse generator 70 and the ventricular
23 pulse generator 72 may include dedicated, independent pulse generators,
24 multiplexed pulse generators, or shared pulse generators. The atrial pulse
25 generator 70 and the ventricular pulse generator 72 are controlled by the

1 microcontroller 60 via appropriate control signals 76 and 78, respectively, to
2 trigger or inhibit the stimulation pulses.

3 The microcontroller 60 further includes timing control circuitry 79 which is
4 used to control the timing of such stimulation pulses (e.g., pacing rate, atrio-
5 ventricular (AV) delay, atrial interconduction (A-A) delay, or ventricular
6 interconduction (V-V) delay, etc.), as well as to keep track of the timing of
7 refractory periods, PVARP intervals, noise detection windows, evoked response
8 windows, alert intervals, marker channel timing (via marker channel logic 81),
9 etc., which is well known in the art.

10 The switch bank 74 includes a plurality of switches for connecting the
11 desired electrodes to the appropriate I/O circuits, thereby providing complete
12 electrode programmability. Accordingly, the switch bank 74, in response to a
13 control signal 80 from the microcontroller 60, determines the polarity of the
14 stimulation pulses (e.g. unipolar, bipolar, combipolar, etc.) and various shocking
15 vectors by selectively closing the appropriate combination of switches (not shown)
16 as is known in the art.

17 Atrial sensing circuits 82 and ventricular sensing circuits 84 may also be
18 selectively coupled to the right atrial lead 20, coronary sinus lead 24, and the right
19 ventricular lead 30, through the switch bank 74, for detecting the presence of
20 cardiac activity in each of the four chambers of the heart. Accordingly, the atrial
21 and ventricular sensing circuits 82 and 84 may include dedicated sense amplifiers,
22 multiplexed amplifiers, or shared amplifiers. The switch bank 74 determines the
23 "sensing polarity" of the cardiac signal by selectively closing the appropriate
24 switches. In this way, the clinician may program the sensing polarity independent
25 of the stimulation polarity.

1 The atrial sensing circuit 82 or the ventricular sensing circuit 84 preferably
2 employ one or more low power, precision amplifiers with programmable gain
3 and/or automatic gain control, bandpass filtering, and a threshold detection circuit,
4 to selectively sense the cardiac signal of interest. The automatic gain control
5 enables the stimulation device 10 to deal effectively with the difficult problem of
6 sensing the low amplitude signal characteristics of atrial or ventricular fibrillation.
7 The outputs of the atrial and ventricular sensing circuits, 82 and 84, are connected
8 to the microcontroller 60 for triggering or inhibiting the atrial and ventricular pulse
9 generators, 70 and 72, respectively, in a demand fashion, in response to the
10 absence or presence of cardiac activity, respectively, in the appropriate chambers
11 of the heart.

12 For arrhythmia detection, the stimulation device 10 utilizes the atrial and
13 ventricular sensing circuits, 82 and 84, to sense cardiac signals for determining
14 whether a rhythm is physiologic or pathologic. As used herein "sensing" is
15 reserved for the noting of an electrical signal, and "detection" is the processing of
16 these sensed signals and noting the presence of an arrhythmia. The timing
17 intervals between sensed events (e.g. P-waves, R-waves, and depolarization
18 signals associated with fibrillation which are sometimes referred to as "F-waves"
19 or "Fib-waves") are then classified by the microcontroller 60 by comparing them
20 to a predefined rate zone limit (e.g. bradycardia, normal, low rate VT, high rate
21 VT, and fibrillation rate zones) and various other characteristics (e.g. sudden
22 onset, stability, physiologic sensors, and morphology, etc.) in order to determine
23 the type of remedial therapy that is needed (e.g. bradycardia pacing, anti-
24 tachycardia pacing, cardioversion shocks or defibrillation shocks, collectively
25 referred to as "tiered therapy").

1 Cardiac signals are also applied to the inputs of an analog-to-digital (A/D)
2 data acquisition system 90. The data acquisition system 90 is configured to
3 acquire intracardiac electrogram signals, convert the raw analog data into digital
4 signals, and store the digital signals for later processing and/or telemetric
5 transmission to an external device 102. The data acquisition system 90 is coupled
6 to the right atrial lead 20, the coronary sinus lead 24, and the right ventricular lead
7 30 through the switch bank 74 to sample cardiac signals across any pair of desired
8 electrodes.

9 The microcontroller 60 is further coupled to a memory 94 by a suitable
10 data/address bus 96, wherein the programmable operating parameters used by the
11 microcontroller 60 are stored and modified, as required, in order to customize the
12 operation of the stimulation device 10 to suit the needs of a particular patient.
13 Such operating parameters define, for example, pacing pulse amplitude, pulse
14 duration, electrode polarity, rate, sensitivity, automatic features, arrhythmia
15 detection criteria, and the amplitude, waveshape and vector of each shocking pulse
16 to be delivered to the patient's heart 12 within each respective tier of therapy.

17 Advantageously, the operating parameters of the stimulation device 10 may
18 be non-invasively programmed into the memory 94 through a telemetry circuit
19 100 in telemetric communication with the external device 102, such as a
20 programmer, transtelephonic transceiver, or a diagnostic system analyzer. The
21 telemetry circuit 100 is activated by the microcontroller 60 by a control signal 106.
22 The telemetry circuit 100 advantageously allows intracardiac electrograms and
23 status information relating to the operation of the stimulation device 10 (as
24 contained in the microcontroller 60 or memory 94) to be sent to the external
25 device 102 through the established communication link 104.

1 In a preferred embodiment, the stimulation device 10 further includes a
2 physiologic sensor 108, commonly referred to as a "rate-responsive" sensor
3 because it is typically used to adjust pacing stimulation rate according to the
4 exercise state of the patient. However, the physiological sensor 108 may further
5 be used to detect changes in cardiac output, changes in the physiological condition
6 of the heart, or diurnal changes in activity (e.g. detecting sleep and wake states).
7 A physiological parameter of the heart, which may be measured to optimize such
8 pacing and to indicate when such pacing may be inhibited or terminated is the
9 stroke volume of the heart. Accordingly, the microcontroller 60 responds by
10 adjusting the various pacing parameters (such as rate, AV Delay, A-A Delay, V-V
11 Delay, etc.) at which the atrial and ventricular pulse generators, 70 and 72,
12 generate stimulation pulses.

13 The stimulation device 10 additionally includes a power source such as a
14 battery 110 that provides operating power to all the circuits shown in FIG. 2. For
15 the stimulation device 10, which employs shocking therapy, the battery 110 must
16 be capable of operating at low current drains for long periods of time, and also be
17 capable of providing high-current pulses (for capacitor charging) when the patient
18 requires a shock pulse. The battery 110 must preferably have a predictable
19 discharge characteristic so that elective replacement time can be detected.
20 Accordingly, the stimulation device 10 can employ lithium/silver vanadium oxide
21 batteries.

22 It can be a primary function of the stimulation device 10 to operate as an
23 implantable cardioverter/defibrillator (ICD) device. That is, it can detect the
24 occurrence of an arrhythmia, and automatically apply an appropriate electrical
25 shock therapy to the heart aimed at terminating the detected arrhythmia. To this

1 end, the microcontroller 60 further controls a shocking circuit 116 by way of a
2 control signal 118. The shocking circuit 116 generates shocking pulses of low (up
3 to 0.5 joules), moderate (0.5 - 10 joules), or high (11 to 40 joules) energy, as
4 controlled by the microcontroller 60. Such shocking pulses are applied to the
5 patient's heart through at least two shocking electrodes, and as shown in this
6 embodiment, selected from the left atrial coil electrode 29, the RV coil electrode
7 36, and/or the SVC coil electrode 38 (FIG. 1). As noted above, the housing 40
8 may act as an active electrode in combination with the RV electrode 36, or as part
9 of a split electrical vector using the SVC coil electrode 38 or the left atrial coil
10 electrode 29 (i.e., using the RV electrode as the common electrode).

11 Cardioversion shocks are generally considered to be of low to moderate
12 energy level (so as to minimize pain felt by the patient), and/or synchronized with
13 an R-wave and/or pertaining to the treatment of tachycardia. Defibrillation shocks
14 are generally of moderate to high energy level (i.e., corresponding to thresholds in
15 the range of 5-40 joules), delivered asynchronously (since R-waves may be too
16 disorganized), and pertaining exclusively to the treatment of fibrillation.
17 Accordingly, the microcontroller 60 is capable of controlling the synchronous or
18 asynchronous delivery of the shocking pulses.

19 As further shown in Fig. 2, the stimulation device 10 is shown as having an
20 impedance measuring circuit 120 including an impedance measuring current
21 source 112 and a voltage measuring circuit 90 (shown in FIG. 2 as an A/D
22 converter), which is enabled by the microcontroller 60 by a control signal 114 for
23 providing stroke volume measurements of the heart. The current source 112
24 preferably provides an alternating or pulsed excitation current. The voltage
25

1 measuring circuitry 90 may also take the form of, for example, a differential
2 amplifier.

3 The uses for an impedance measuring circuit 120 include, but are not
4 limited to, lead impedance surveillance during the acute and chronic phases for
5 proper lead positioning or dislodgment; detecting operable electrodes and
6 automatically switching to an operable pair if dislodgment occurs; measuring a
7 respiration parameter (for example, tidal volume, respiration rate, minute
8 ventilation or volume, abnormal or periodic breathing); measuring thoracic
9 impedance for determining shock thresholds and shock timing (corresponding to
10 the diastolic time); detecting when the device has been implanted; measuring a
11 cardiac parameter (such as, stroke volume, wall thickness, left ventricular volume,
12 etc.); and detecting the opening of the valves, etc. In the present embodiment, the
13 impedance measuring circuit is used to monitor left heart disease and provides
14 appropriate stimulation therapy, such as altering rate, AV , A-A , or V-V delays.
15 The impedance measuring circuit 120 is advantageously coupled to the switch
16 bank 74 so that any desired electrode may be used. Impedance may also be useful
17 in verifying hemodynamic collapse to confirm that ATP has failed and/or VF has
18 begun.

19 The microcontroller 60 is coupled to the voltage measuring circuit 90 and
20 the current source 112 for receiving a magnitude of the established current and a
21 magnitude of the monitored voltage. The microcontroller 60, operating under
22 program instructions, divides the magnitude of the monitored or measured voltage
23 by the magnitude of the established current to determine an impedance value.
24 Once the impedance signals are determined, they may be delivered to the memory
25 94 for storage and later retrieved by the microcontroller 60 for therapy adjustment

1 or telemetry transmission. The telemetry circuitry receives the impedance values
2 from the microcontroller 60 and transmits them to the external programmer. The
3 impedance value may then be monitored by the patient's physician to enable the
4 physician to track the patient's condition.

5 The impedance measuring circuit 120 is advantageously coupled to the
6 switch bank 74 so that any desired electrode may be used. The current source 112
7 may be programmably configured between a desired pair of electrodes, and the
8 voltage measuring circuit 90 may be programmably configured between the same
9 or preferably a different pair of electrodes.

10

Exemplary Inventive Embodiments Overview

11 In the embodiments below, various configurations of electrodes are
12 provided that permit measurements of left ventricular function to be made for both
13 monitoring and therapy delivery. The different configurations can have a variety
14 of polarities. For example, bipolar, tripolar and quadrapolar configurations can be
15 used. Bipolar configurations are configurations that utilize any two suitable
16 electrodes; tripolar configurations are configurations that use any three suitable
17 electrodes; and quadrapolar configurations are configurations that use any four
18 suitable configurations. The different configurations can be used to measure one
19 or more physiological parameters for assessing or determining a patient's cardiac
20 condition based on left heart impedance measurements. In the discussion that
21 follows, certain specific electrode configurations are described to provide non-
22 limiting examples of various bipolar, tripolar, and quadrapolar configurations that
23 can be used to facilitate measurement of left ventricular function and the
24 measurement of other parameters associated with heart function.

1

2 **Respiration**

3 In conjunction with ventricular pacing of the heart, one parameter
4 associated with the heart which is prominent in ascertaining the effectiveness of
5 the cardiac pacing is respiration (or a respiration parameter, for example, tidal
6 volume, respiration rate, minute ventilation or volume, abnormal or periodic
7 breathing). This requires ascertaining the condition of the lung tissue and may
8 also be measured by the device 10 illustrated in FIG. 3. This may be preferably
9 accomplished by sourcing the current between the housing 40 and right ventricular
10 coil electrode 36 while measuring the voltage between the left ventricular tip
11 electrode 25 and housing 40.

12 One limitation in the use of a pacing electrode, or a pacing electrode pair, in
13 the cardiac vein is that the local impedance is influenced by many factors. With
14 the system illustrated in FIG. 4, a three-point impedance measurement is obtained
15 which is less affected by the local impedance of the electrode or electrodes in the
16 great vein. As a result, an accurate measure of the left ventricular impedance is
17 obtained to provide corresponding accurate monitoring of stroke volume and the
18 respiration parameter.

19 In measuring the respiration parameter, a current path is established
20 between the left ventricular tip electrode 25 and the housing 40. Once established,
21 the voltage measuring circuit measures the voltage between the left ventricular
22 ring electrode 26 and the housing 40. This effectively provides an impedance
23 measurement corresponding to the respiration parameter. The resulting measured
24 voltage signal will have both cardiac and respiratory components. However, the
25

1 cardiac component will be smaller than that from intracardiac electrodes and can
2 be readily filtered in a manner known in the art.

3 FIG. 5 shows another electrode configuration that can be used to measure
4 impedance. In this configuration, a current path is established between left atrial
5 ring electrode 28 and the housing 40. The voltage measuring circuit then
6 measures the voltage between the left atrial ring electrode 27 and the housing 40.

7 FIG. 6 shows another electrode configuration that can be used to measure
8 impedance. In this configuration, a current path is established between left atrial
9 coil electrode 29 and the housing 40. The voltage measuring circuit then measures
10 the voltage between the left atrial ring electrode 27 and the housing 40.

11 FIG. 7 shows a tripolar electrode configuration that can be used to measure
12 impedance. In this configuration, a current path is established between right
13 ventricular ring electrode 34 and the housing 40. The voltage measuring circuit
14 then measures the voltage between the left atrial ring electrode 27 and the housing
15 40.

16 Alternatively, as will be appreciated by those skilled in the art, left atrial
17 ring electrodes 27 and 28 can be utilized for the respiration parameter
18 measurements. In this case, shown in FIG. 8, the electrical current path is
19 established between the first atrial ring electrode 27 and the housing 40 and the
20 resulting voltage is measured between the second atrial ring electrode 28 and the
21 housing 40. As will also be appreciated by those skilled in the art, an alternative
22 embodiment could employ a single electrode in a cardiac vein with appropriate
23 filtering to extract the respiration parameter component of the impedance signal.

1 **Left Ventricular Wall Dynamics**

2 In an alternate embodiment, shown in FIG. 9, the device 10 can be coupled
3 to a different electrode configuration for measuring left ventricular wall dynamics.
4 Here it will be seen that the current source 112 is coupled between the left
5 ventricular ring electrode 26 and the left ventricular tip electrode 25. The voltage
6 measuring circuit 90 is also coupled between left ventricular ring electrode 26 and
7 left ventricular tip electrode 25. Since the left ventricular electrodes 25 and 26 are
8 preferably positioned so as to be located on the left ventricular free wall, the
9 voltage signal measured by the voltage measuring circuit 90 will predominantly
10 represent myocardium impedance for measuring left ventricular wall dynamics,
11 such as the wall thickness.

12 FIG. 10 shows an alternate bipolar electrode configuration that can be
13 utilized to measure impedance for measuring left ventricular wall dynamics. In
14 this embodiment, the current source 112 is coupled between the left atrial ring
15 electrode 27 and the left ventricular tip electrode 25. The voltage measuring
16 circuit 90 is coupled between the left atrial ring electrode 27 and the left
17 ventricular tip electrode 25.

18 FIG. 11 shows an alternate tripolar electrode configuration that can be
19 utilized to measure impedance for measuring left ventricular wall dynamics. In
20 this embodiment, the current source 112 is coupled between the left atrial ring
21 electrode 27 and the left ventricular tip electrode 25. The voltage measuring
22 circuit 90 is coupled between the left atrial ring electrode 28 and the left
23 ventricular tip electrode 25.

24 FIG. 12 shows an alternate quadrapolar electrode configuration that can be
25 utilized to measure impedance for measuring left ventricular wall dynamics. In

1 this embodiment, the current source 112 is coupled between the left atrial ring
2 electrode 28 and the left ventricular tip electrode 25. The voltage measuring
3 circuit 90 is coupled between the left atrial ring electrode 27 and the left
4 ventricular ring electrode 26.

5 Alternatively, the current source 112 can be coupled between a right
6 ventricular electrode 32 or 34 and the housing 40 with voltage measurement still
7 performed between electrodes 26 and 25 as shown in FIG. 13. As will be
8 appreciated by those skilled in the art, an alternative embodiment could employ a
9 single electrode within a cardiac vein on the left ventricular free wall and
10 appropriate filtering to extract the cardiac component in the impedance signal.

11 FIG. 14 shows an alternate tripolar electrode configuration that can be
12 utilized to measure impedance for measuring left ventricular wall dynamics. In
13 this embodiment, the current source 112 is coupled between the right ventricular
14 ring electrode 34 and the housing 40. The voltage measuring circuit 90 is coupled
15 between the left atrial ring electrodes 27, 28.

16 FIG. 15 shows an alternate electrode configuration that can be utilized to
17 measure impedance for measuring left ventricular wall dynamics. In this
18 embodiment, the current source 112 is coupled between the right ventricular ring
19 electrode 34 and the housing 40. The voltage measuring circuit 90 is coupled
20 between the left atrial ring electrode 28 and the left ventricular ring electrode 26.

21

22 Left Ventricular Volume Measurements

23 The current source 112 and voltage measuring circuit 90 may be employed
24 in still further different configurations that facilitate left ventricular volume
25 measurements. Here it will be seen that the left ventricular volume measurements

1 are made with electrode pairs which are selected to measure a cross-section of the
2 left ventricle. This can be done by determining the trans-chamber impedance.

3 For example, FIG. 16 shows a configuration that can be utilized to monitor
4 stroke volume. In this configuration, the current source 112 can be configured to
5 provide an alternating current between the housing 40 and the right ventricular coil
6 electrode 36. As this current is established, the voltage across the left ventricle is
7 measured between the left ventricular tip electrode 25 and the right ventricular coil
8 electrode 36. This gives an accurate measure of the left ventricular impedance and
9 will provide an accurate contraction signature.

10 FIG. 17 shows another configuration that can be utilized to determine trans-
11 chamber impedance. Here, the current source 112 is coupled between the right
12 ventricular tip electrode 32 and the left ventricular ring electrode 26, while the
13 voltage measuring circuit 90 is coupled between the right ventricular ring
14 electrode 34 and the left ventricular tip electrode 25.

15 FIG. 18 shows a bipolar configuration that can be utilized to determine
16 trans-chamber impedance. Here, the current source 112 is coupled between the
17 right ventricular ring electrode 34 and the left ventricular ring electrode 26, and
18 the voltage measuring circuit 90 is coupled between the right ventricular ring
19 electrode 34 and the left ventricular ring electrode 26.

20 In accordance with the embodiment shown in FIG. 18, the current source
21 112 is coupled between the right ventricular ring electrode 34 and the left
22 ventricular ring electrode 26, while the voltage measuring circuit 90 is coupled
23 between the right ventricular ring electrode 34 and the left ventricular tip electrode
24 25.

1 Preferably, the voltage measuring circuitry 90 measures the voltage
2 between the right ventricular electrode 32 or 34 which was not used in the
3 establishing of the electrical current path and the left ventricular tip electrode 25.
4 The voltage signal thus measured will be representative of the cross-section of the
5 left ventricle and yield an accurate representation of the left ventricular volume.

6 In yet another alternative embodiment for measuring left ventricular
7 volume (a quadrapolar configuration), shown in FIG. 20, it will be noted that the
8 current source 112 is coupled between the right ventricular ring electrode 34 and
9 the first left atrial ring electrode 27, while the voltage measuring circuit 90 is
10 coupled between the right ventricular tip electrode 32 and the second left atrial
11 ring electrode 28.

12 Alternatively, shown in FIG. 21, the current source 112 can be coupled
13 between the right ventricular ring electrode 34 and the housing 40, while the
14 voltage measuring circuit 90 is coupled between the right ventricular tip electrode
15 32 and the second left atrial ring electrode 28.

16 In yet another embodiment, a quadrapolar configuration shown in FIG. 22,
17 is provided for measuring the left ventricular volume. Here, the current source
18 112 establishes an electrical current between the right ventricular ring electrode 34
19 and the first left atrial ring electrode 27. While this current is established, the
20 voltage measuring circuit 90 measures the voltage between the right ventricular tip
21 electrode 32 and the second left atrial ring electrode 28 . The resulting voltage
22 signal measured by the voltage measuring circuit 90 will represent the impedance
23 across the cross-section of the left ventricle to provide an accurate representation
24 of the left ventricular volume.

1 The impedance measurements may be obtained by establishing an electrical
2 current between the electrode of an electrode pair and measuring the voltage
3 between the electrode pair during the current establishment. Mechanical
4 activation of an associated chamber will cause a significant deflection in the
5 resulting voltage signal or impedance. This provides a valuable tool for
6 monitoring systolic and diastolic time intervals of the heart. For example, an
7 impedance measurement from a chamber may be taken to indicate the mechanical
8 activation of that chamber as for example the electrode pair, 32 and 34, in the right
9 ventricle to indicate the timing of the right ventricular contraction and the bipolar
10 pair, 25 and 26, to indicate the timing of the left ventricular contraction. From the
11 different times of mechanical activation, systolic and diastolic time intervals may
12 be ascertained by comparing these times to those based on electrogram
13 measurements.

14 As can be seen from the foregoing, the present invention provides a system
15 and method for measuring a physiological parameter of, or associated with, a
16 patient's a heart. In each of the foregoing embodiments, a current flow is
17 established through a left side of the heart and a voltage is measured between a
18 first location on or in the left side of the heart and a second location within the
19 human body while establishing the current flow. This preferably includes
20 implanting a first electrode within the coronary sinus and/or a vein of the heart,
21 implanting a second electrode within the body, establishing a current within the
22 body, and measuring a voltage between the first and second electrodes while
23 establishing the current flow. As a result, impedance measurements may be
24 obtained which provide valuable information for the patient's physician to
25 diagnostically monitor and use which are indicative of physiological parameters

1 of, or associated with, the heart for those patients which require cardiac rhythm
2 management associated with the left side of the heart.

3 Although the invention has been described in language specific to structural
4 features and/or methodological steps, it is to be understood that the invention
5 defined in the appended claims is not necessarily limited to the specific features or
6 steps described. Rather, the specific features and steps are disclosed as preferred
7 forms of implementing the claimed invention.

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